

REMARKS

The Applicants respectfully request reconsideration of the present application in view of the foregoing amendments and in view of the reasons that follow.

I. Status of the Claims

The Applicants thank the Examiner for withdrawing the previous 35 U.S.C. §§ 101, 112 rejections.

Non-elected claims 5-10, and 13-14 are herein cancelled to be in compliance with 37 C.F.R. 1.121(c). The Applicants reserve the right to pursue the subject matter of the canceled claims in subsequent divisional applications. No new matter has been introduced, and claims 1-4, and 11-12 are currently pending to be examined on their merits.

II. 35 U.S.C. § 102 Rejections

The Applicants thank the Examiner for withdrawing the previous 35 U.S.C. § 102 (b) rejections over Schwarz. The 35 U.S.C. § 102 (b) anticipation rejections over Tajima (US 2002/0192177) for claims 1-4, and 11-12 are maintained. The Office alleges that by practicing the process of Tajima, one would inherently be practicing the process claimed in the present application. The Applicants respectfully traverse.

During the anagen phase of a normal hair cycle, a hair shaft grows downwards into the skin, **both** enlarging its diameter (i.e., **thickening**) **and elongating** its length. The anagen phase is subsequently followed by the regressing catagen phase, which is followed by the quiescent telogen phase. During the catagen phase, the thickness and the length of the hair are reduced. The hair then grows and returns to its thickness and length in another anagen phase, repeating the cycle. A description of hair cycle, can be found, for example, in Stenn et al., page 458, *Physiological Reviews* 81(1), 2001, pp. 449-494 (Exhibit A) or Figure 1 in Muller-Rover et al., *J. Invest Dermatol* 117(1), 2001, pp. 3-15 (Exhibit B).

The hair “thickening” referred to by the Office with respect to the diagram from the Britannica Encyclopedia points to the thickening of the diameter of hair accompanying the growth of hair during only the anagen phase. See Office Action, page 8. In contrast to such transient event occurring only in a phase of a natural hair cycle, the claimed methods in the present application are directed to promoting thickening and growth of the hair after repetitions of hair cycles. In other words, the claim methods facilitate the recovery of the hair to its thickness in its previous anagen phase after repetitions of hair cycles, instead of promoting thickening the hair merely during one phase of a hair cycle. Thus, the “thickening” as alleged by the Office is not analogous to the thickening recited in the present claims.

This thickening effect, as recited in the present claims, further distinguishes the present application from Tajima. Hair loss in human beings is caused by transition of the hair from the anagen phase into the catagen phase before the thickness of the hair can acquire its original state. As a consequence, the hair gradually loses its thickness after successive repetitions of the cycle and never recovers its original thickness. See e.g., Abstract in Tajima et al., *J Dermatol Sci* 45(2), 2007, p93-103 (Exhibit C).

Tajima does not teach or disclose a method for maintaining and promoting the thickness of hair, as recited in claim 1 of the present application. The claimed method provides a composition that is capable of increasing the expression of keratinocyte growth factor (FGF-7) in hair follicle cells, upon the application of the composition to the scalp of a subject undergoing treatment. By contrast, Tajima discloses a hair tonic containing at least one active ingredient and a carrier. According to Tajima, the disclosed hair tonic provides superior hair loss preventing action, as well as hair growth promoting action. Nowhere does Tajima disclose that its hair tonic composition promotes the thickening of hair, as recited by claim 1.

Additionally, Tajima discloses a test for measuring the ability of its hair tonic to promote the growth of new hair (“hair growth promoting action test”) in mice. See Example 5 in the present application. According to Tajima, animals in the catagen phase of the hair growth cycle are used to measure the ability of the hair tonic to induce growth of new hair within the test

area. Tajima merely provides a hair tonic for stimulating the growth of new hair. Nowhere does Tajima disclose or even suggest that its hair tonic thickens hair, as recited in the present claims.

As mentioned above, nowhere does Tajima disclose its hair tonic to **thicken hair**, as recited in claim 1. In fact, the Applicants respectfully submit that the Office has mischaracterized the claimed methods by asserting that increasing the expression of keratinocyte growth factor in hair follicle cells is merely a new function of a known agent that is known in the prior art. The Applicants respectfully traverse.

The claims of the present application are not directed to a new function or a mechanism of action for FGF-7. Instead, claim 1 recites a method for maintaining and promoting the **thickness of hair** using FGF-7. The phrase “hair thickening” refers **to increasing the diameter of the hair** using a composition that has an agent capable of increasing the expression of keratinocyte growth factor (FGF-7). *See* page 7, lines 1-16 in the Specification. It is generally known in the art that because of the complex bimolecular interactions, an agent that can promote hair growth does not automatically thicken the hair. Thus, Tajima and the present application aim to achieve different mechanisms. Because nowhere does Tajima show an intent to achieve the same mechanism as the present application, the former cannot anticipate the later by inherency. *See Jansen v. Rexall Sunudown* 342 F.3d 1329, 1333, 68 USPQ2d 1154, 1158 (Fed. Cir. 2003).

Because Tajima does not teach each and every element of the claims recited in the present application and it does not anticipate the present claims by inherency, the Applicants respectfully request that the anticipation rejections be withdrawn.

III. **Double Patenting**

Claims 1-4, and 11-12 are rejected on the ground of nonstatutory double patenting. The Applicants request that the rejections be held in abeyance until the other rejections are overcome in the present application. The Applicants request that if double patenting becomes the last

remaining rejection in the present application, the Examiner contact the undersigned representative to consider filing a terminal disclaimer if warranted to overcome such rejection.

CONCLUSION

The Applicants believe that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

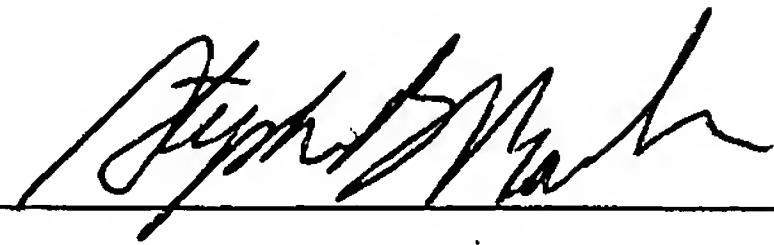
It is acknowledged that the foregoing amendments are submitted after final rejection. However, because the amendments do not introduce new matter or raise new issues, and because the amendments either place the application in condition for allowance or at least in better condition for appeal, entry thereof by the Examiner is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing or a credit card payment form being unsigned, providing incorrect information resulting in a rejected credit card transaction, or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, the Applicants hereby petition for such extension under 37 C.F.R. § 1.136 and authorize payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

Date Oct. 17, 2008

By 

FOLEY & LARDNER LLP
Customer Number: 22428
Telephone: (202) 672-5569
Facsimile: (202) 672-5399

Stephen B. Maebius
Attorney for Applicants
Registration No. 35,264